TRAQ – Human Ethics Module

Health Sciences Research Ethics Board (HSREB)

Applying for HSREB Certification

Researcher Coordinator's User Manual

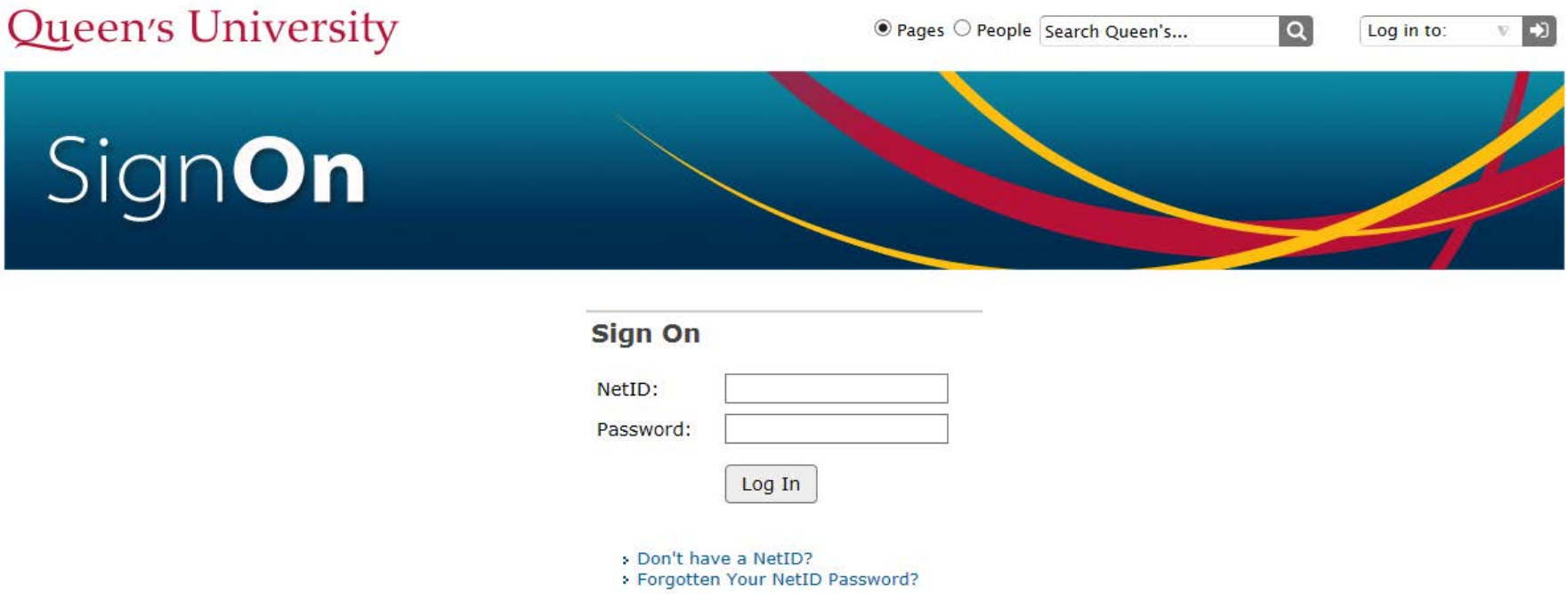
Rev. June 2015

Accessing the TRAQ Researcher Portal

- Queen's faculty and staff should use their regular Queen's NetID and strong password* to log into the TRAQ Researcher Portal through MyQueensU/SOLUS. (Once in MyQueensU, click on My Applications, and then on Go to the TRAQ Researcher Portal hyperlink.)

- The Researcher Portal is also available through the TRAQ website.

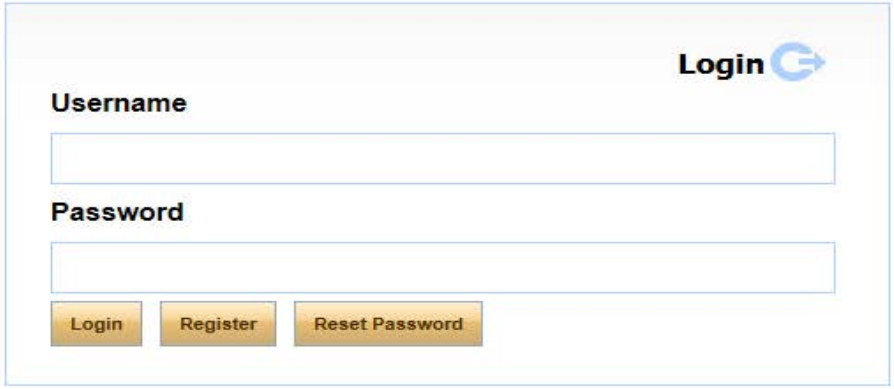
**Information regarding managing your Queen's NetID and strong password is available on the ITS website.*



Accessing the Researcher Portal (Cont.)

- Queen's students and external users, trying to log in for the **first time**, will need to complete the Self Registration Form before they can access the Researcher Portal. Once you have registered, you will receive an automatic email with instructions on setting up your own password. From then on, you will access the Researcher Portal through the Post-Registration Login Site.

- When logging in through the Post Registration Login site, your username is the email address provided at the time of registration.



Researcher Portal – Describing the Homepage

Tools for TRAQ
Research at Queen's
Queen's UNIVERSITY
Click on Apply New to access the Human Ethics applications.
APPLY NEW
News
Useful Links
Settings
Role : Principal Investigator
Applications (Saved - Not Submitted) (1)
Applications (Submitted - Requiring My Attention) (0)
My Reminders (0)
Applications (Submitted - Under Review) [Click here...]
Applications (Submitted - Post Review) [Click here...]
Applications (Withdrawn) [Click here...]
Role: Project Team Member
Applications (Saved - Not Submitted) (0)
Applications (Submitted - Requiring My Attention) (0)
My Reminders (0)
Applications (Submitted - Under Review) [Click here...]
Applications (Submitted - Post Review) [Click here...]
Applications (Withdrawn) [Click here...]

All users have **Principal Investigator** and **Project Team Member** roles. Depending on your role in a particular study, you will be able to access your files (Human Ethics and Biohazard certifications, and TRAQ DSS Form/Agreement Review applications) under one role or the other.

Starting a New Human Ethics Form

Any research project involving human participants, **whether funded or not**, must receive ethics approval of one of the Ethics Boards prior to the start of the project.

- Non-Health Sciences (Social Sciences) submit to the General Research Ethics Board (GREB)
- Health Sciences and affiliated teaching hospitals submit to Health Sciences Research Ethics Board (HSREB)

New Application Forms

GREB

Application Name	Description	Status
GENERAL RESEARCH ETHICS BOARD APPLICATION FORM for ETHICS CLEARANCE (Social Sciences and Humanities)	Updated form - Ja	

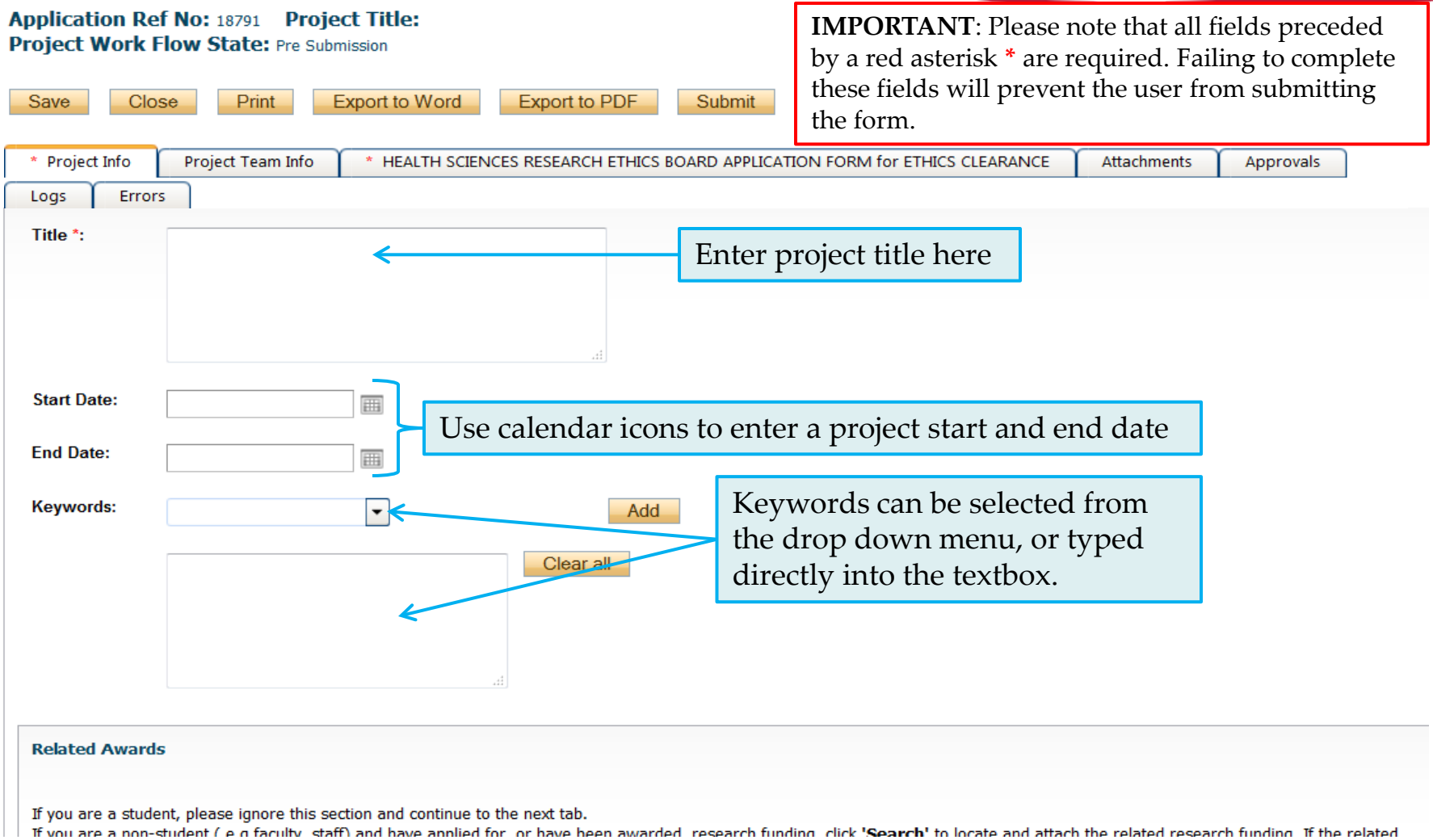
HSREB

Application Name	Description	Status
HEALTH SCIENCES RESEARCH ETHICS BOARD APPLICATION FORM for ETHICS CLEARANCE	HSREB form - upd	
Health Sciences Research Ethics Board Short Form for Critical Enquiry, Chart reviews, Questionnaires, Surveys	To be used for: chart review, critical enquiry etc.	Open

The names of the forms are hyperlinks, click on them once to open a blank application.

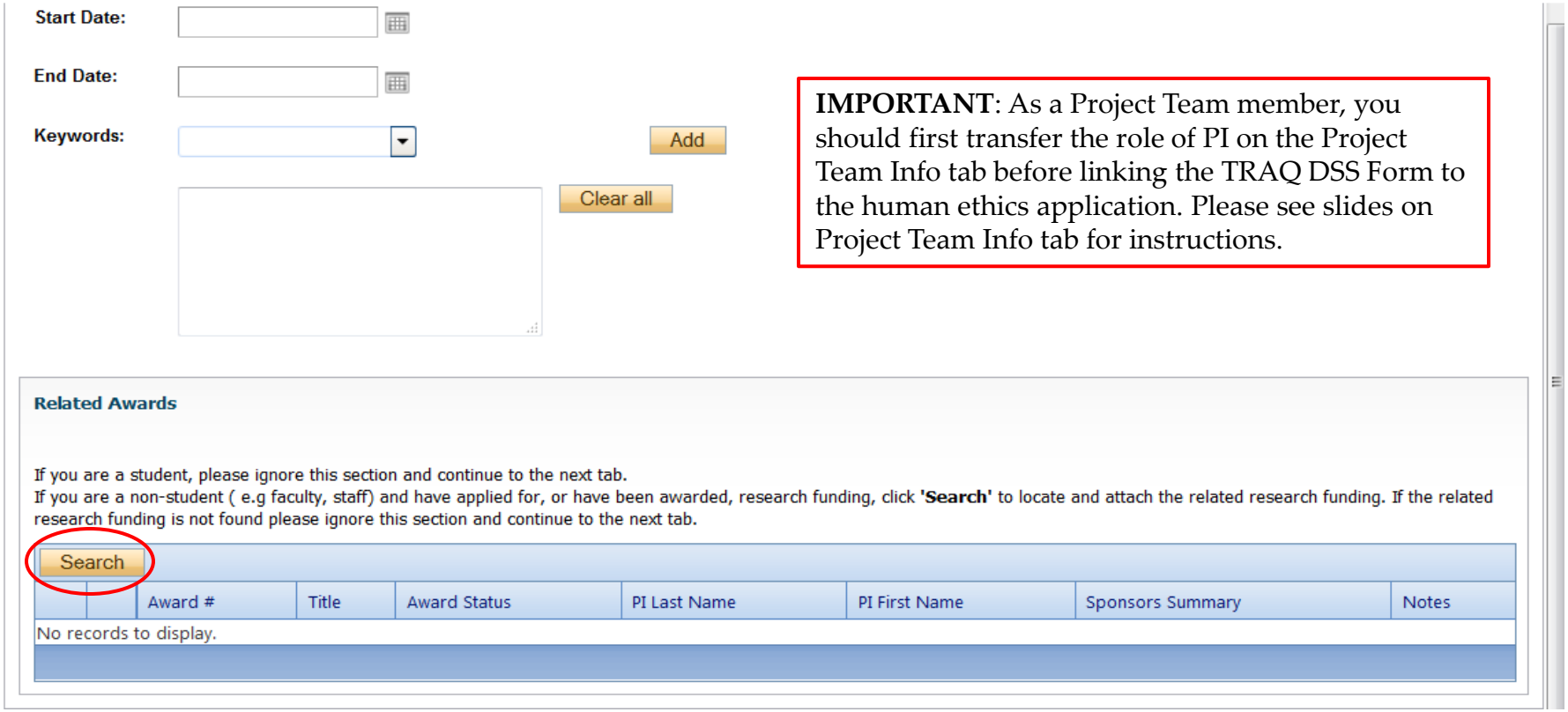
** HSREB applicants must choose between two application forms: the long form and short form for low risk studies. Please contact the Ethics Coordinator of the HSREB if you are unsure which form you should be completing.*

Project Info tab


Application Ref No: 18791 Project Title:
Project Work Flow State: Pre Submission
Save
Close
Print
Export to Word
Export to PDF
Submit
IMPORTANT: Please note that all fields preceded by a red asterisk * are required. Failing to complete these fields will prevent the user from submitting the form.
* Project Info
Project Team Info
* HEALTH SCIENCES RESEARCH ETHICS BOARD APPLICATION FORM for ETHICS CLEARANCE
Attachments
Approvals
Logs
Errors
Title *:
Enter project title here
Start Date:
End Date:
Use calendar icons to enter a project start and end date
Keywords:
Add
Clear all
Keywords can be selected from the drop down menu, or typed directly into the textbox.
Related Awards
If you are a student, please ignore this section and continue to the next tab.

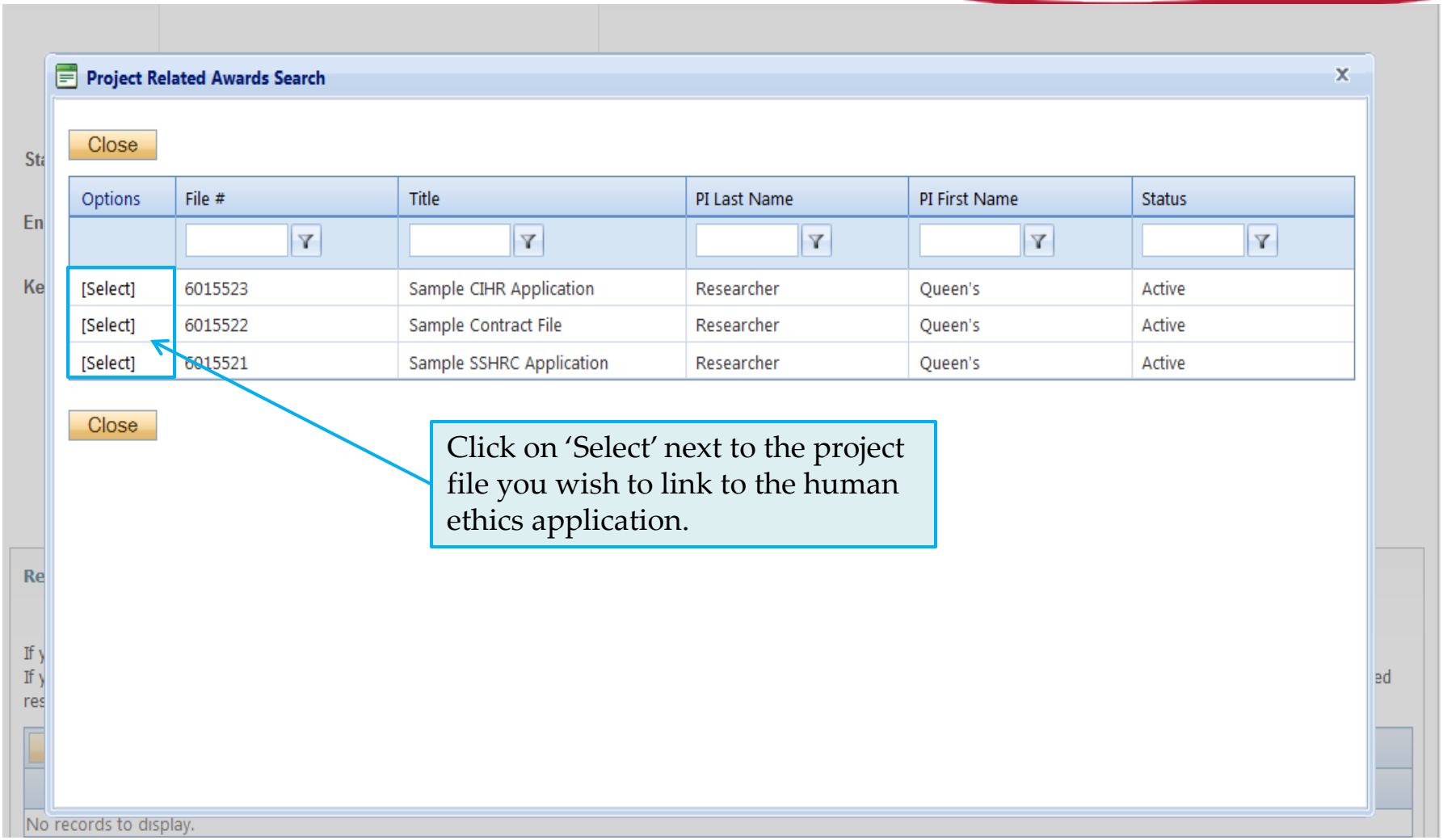
Project Info tab – Related Awards

- If the PI's project is receiving funding, either through a grant or contract, it is important to link the TRAQ DSS Form to the human ethics application.
- Use the side bar to scroll down to the 'Related Awards' section of the Project Info tab screen and click on the yellow 'Search' button to view the PI's submitted TRAQ DSS Forms.


Start Date:
End Date:
Keywords:
Add
Clear all
Related Awards
If you are a student, please ignore this section and continue to the next tab.
If you are a non-student (e.g faculty, staff) and have applied for, or have been awarded, research funding, click 'Search' to locate and attach the related research funding. If the related research funding is not found please ignore this section and continue to the next tab.
Search
Award #
Title
Award Status
PI Last Name
PI First Name
Sponsors Summary
Notes
No records to display.

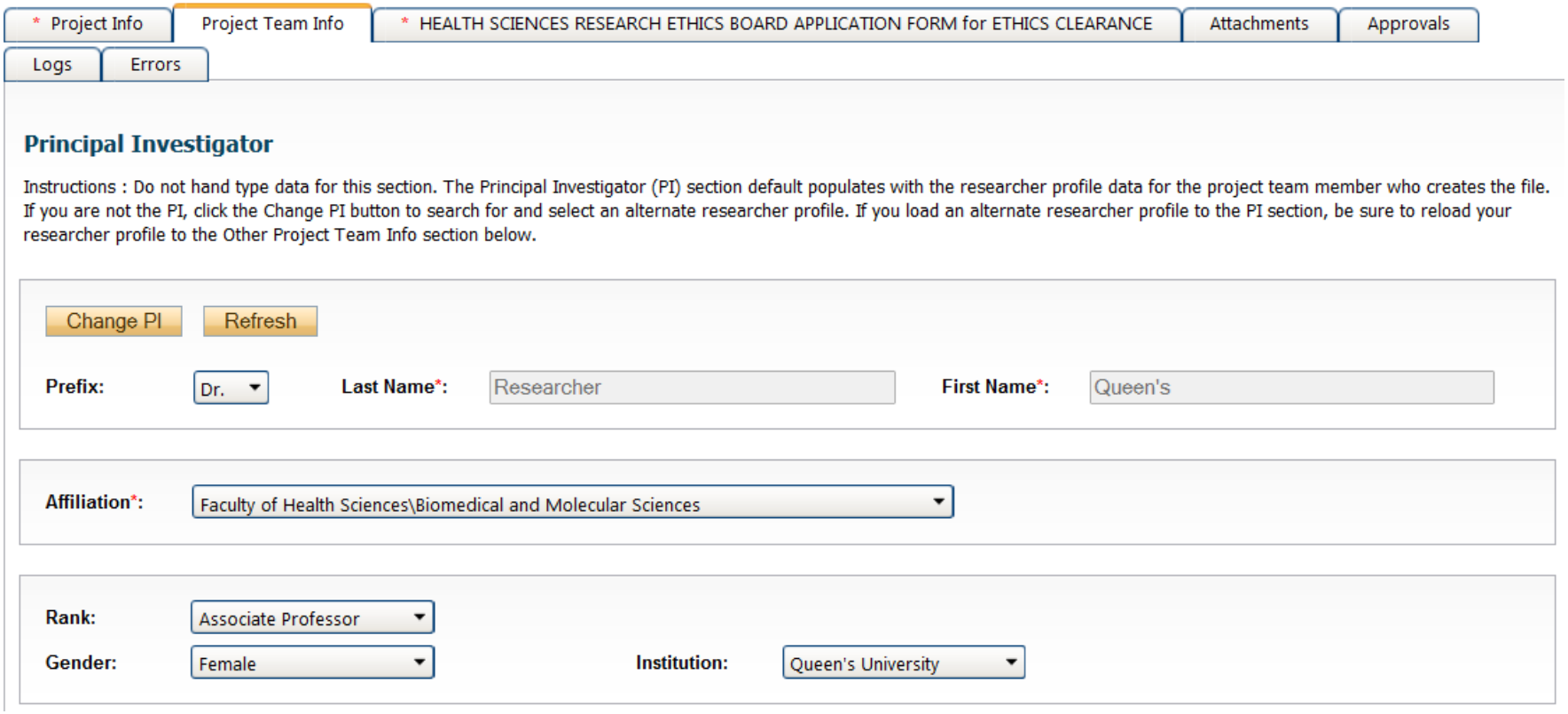
IMPORTANT: As a Project Team member, you should first transfer the role of PI on the Project Team Info tab before linking the TRAQ DSS Form to the human ethics application. Please see slides on Project Team Info tab for instructions.

Project Info tab – Related Awards (Cont.)



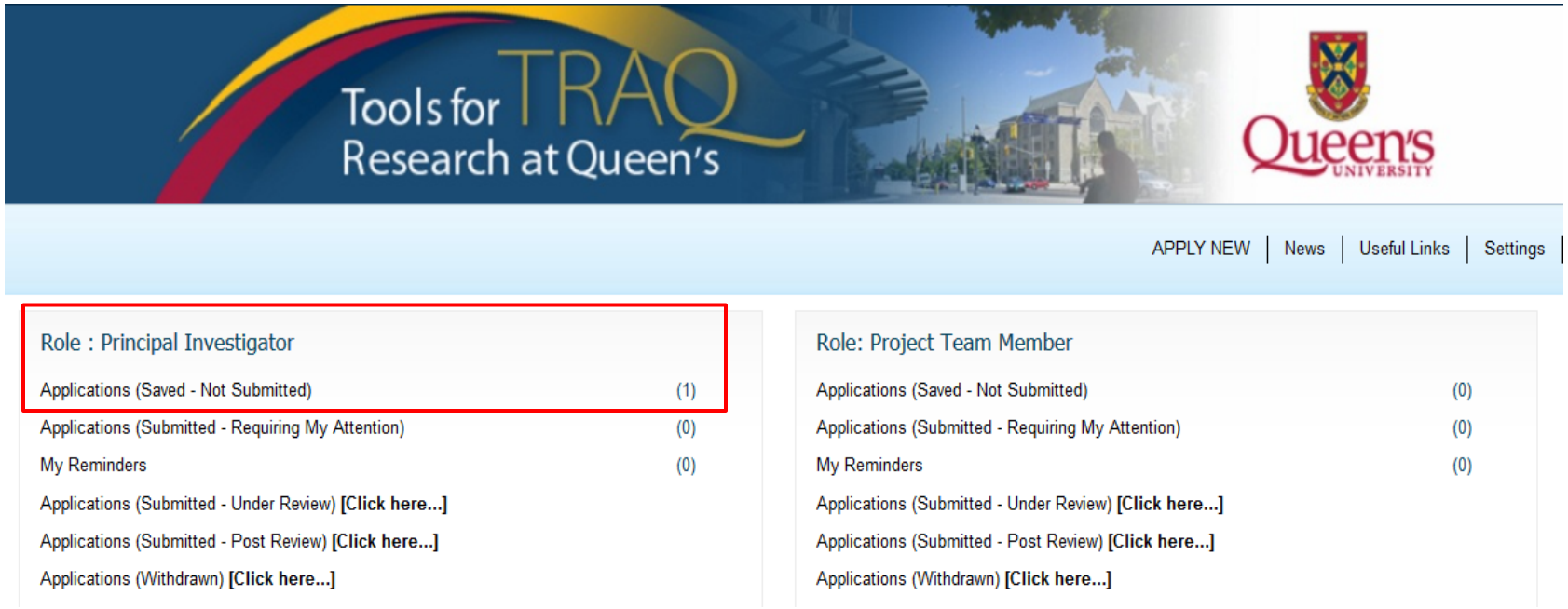
Project Team Info tab

- The top section of the Project Team Info tab (Principal Investigator section) is automatically filled out with the information of the person who created the application. If you click the Save and Close buttons, you will see that the application is still available to you under **Role: Principal Investigator**.


* Project Info
Project Team Info
* HEALTH SCIENCES RESEARCH ETHICS BOARD APPLICATION FORM for ETHICS CLEARANCE
Attachments
Approvals
Logs
Errors
Principal Investigator
Instructions : Do not hand type data for this section. The Principal Investigator (PI) section default populates with the researcher profile data for the project team member who creates the file. If you are not the PI, click the Change PI button to search for and select an alternate researcher profile. If you load an alternate researcher profile to the PI section, be sure to reload your researcher profile to the Other Project Team Info section below.
Change PI
Refresh
Prefix:
Dr.
Last Name*:
Researcher
First Name*:
Queen's
Affiliation*:
Faculty of Health Sciences\Biomedical and Molecular Sciences
Rank:
Associate Professor
Gender:
Female
Institution:
Queen's University

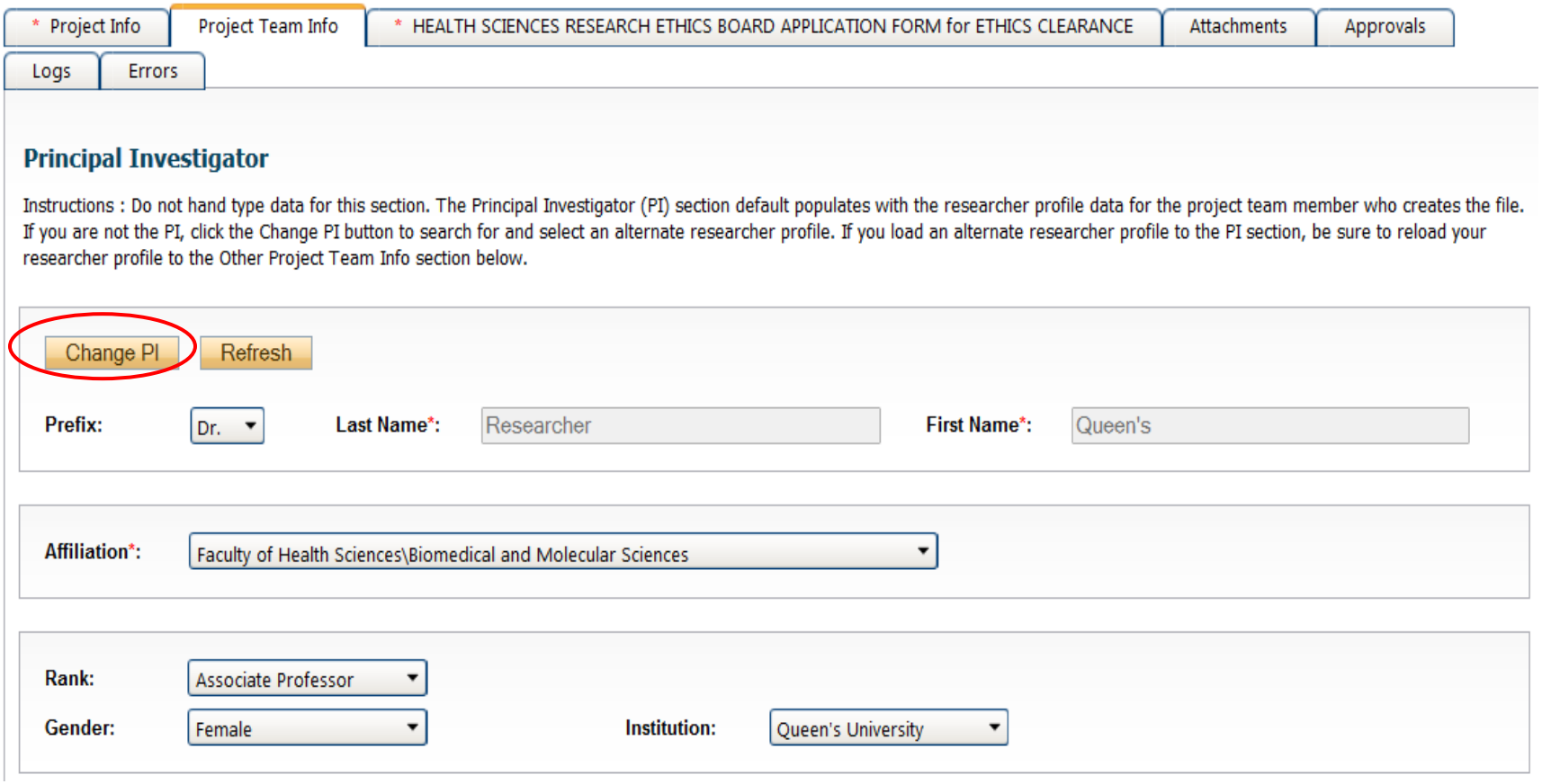
PI Role versus Project Team Member Role

- When a new application is created, TRAQ automatically designates the creator of the application as PI.
- The role of the applicant from PI to Project Team Member will need to be modified to ensure the application will follow the proper process. This can be done at any point during the completion of the form.
- As long as the applicant remains PI the application will continue to be accessible from the TRAQ Researcher Portal home page under **Role: Principal Investigator**.


Tools for TRAQ
Research at Queen's
Queen's UNIVERSITY
APPLY NEW | News | Useful Links | Settings
Role : Principal Investigator
Applications (Saved - Not Submitted) (1)
Applications (Submitted - Requiring My Attention) (0)
My Reminders (0)
Applications (Submitted - Under Review) [Click here...]
Applications (Submitted - Post Review) [Click here...]
Applications (Withdrawn) [Click here...]
Role: Project Team Member
Applications (Saved - Not Submitted) (0)
Applications (Submitted - Requiring My Attention) (0)
My Reminders (0)
Applications (Submitted - Under Review) [Click here...]
Applications (Submitted - Post Review) [Click here...]
Applications (Withdrawn) [Click here...]

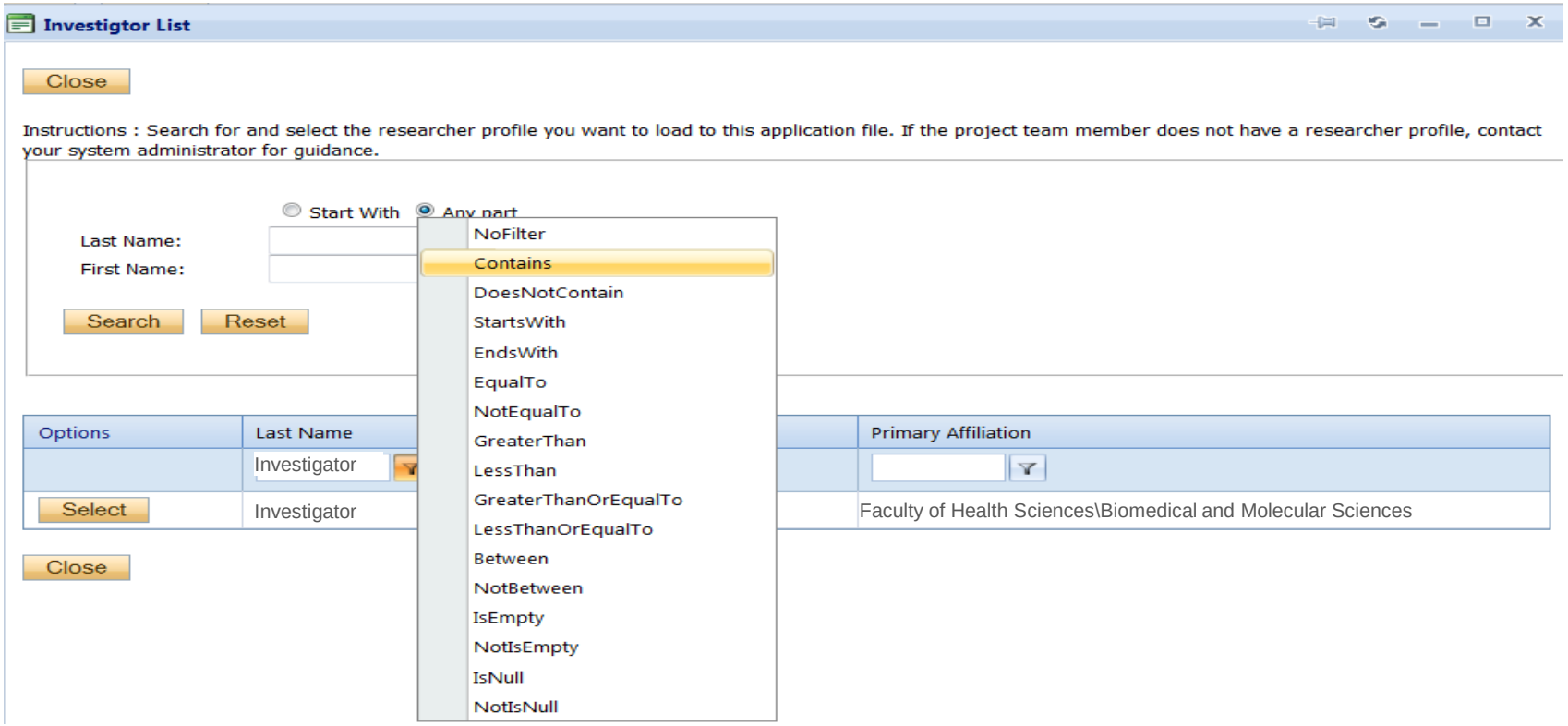
Project Team Info Tab – Change PI

- To change the role of PI over to another researcher, click on Change PI. **Important: DO NOT change P.I.'s "Last Name" and "First Name" manually – always use "Change PI" feature.**


* Project Info
Project Team Info
* HEALTH SCIENCES RESEARCH ETHICS BOARD APPLICATION FORM for ETHICS CLEARANCE
Attachments
Approvals
Logs
Errors
Principal Investigator
Instructions : Do not hand type data for this section. The Principal Investigator (PI) section default populates with the researcher profile data for the project team member who creates the file. If you are not the PI, click the Change PI button to search for and select an alternate researcher profile. If you load an alternate researcher profile to the PI section, be sure to reload your researcher profile to the Other Project Team Info section below.
Change PI
Refresh
Prefix:
Dr.
Last Name*:
Researcher
First Name*:
Queen's
Affiliation*:
Faculty of Health Sciences\Biomedical and Molecular Sciences
Rank:
Associate Professor
Gender:
Female
Institution:
Queen's University

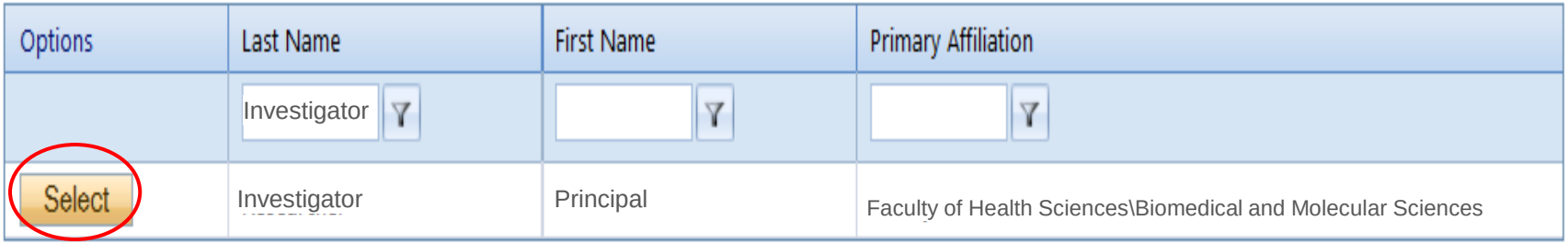
Transferring PI Role to Another Researcher

- Search the Investigator List for the name of the person to be assigned as PI. The list can be searched in a variety of ways, i.e. type the last name of the person in the “Last Name” field, use the filter beside it to select a search criteria such as “EqualTo” or “Contains”.



Transferring PI Role to Another Researcher

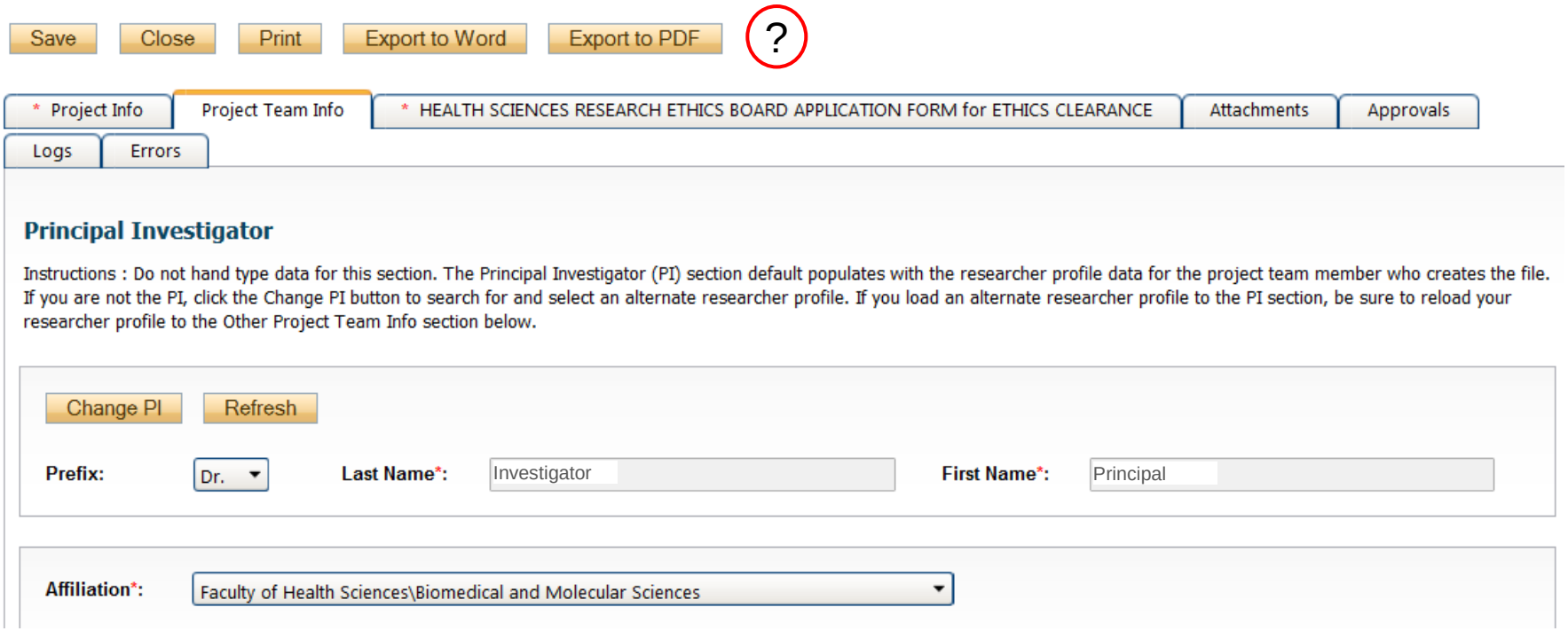
- Once you've identified your PI – click on Select.



- If you are unable to identify the person you are looking for from the investigators list, please email the TRAQ Helpdesk (traq@queensu.ca). Your email should include the person's full name, title, business address and email address. You will be notified as soon as the person has been added to the investigators list and will then be able to transfer the PI role over to them.

Transferring PI Role to Another Researcher (Cont.)

- Project Team Info will automatically be updated with PI's information.
- At this point, you will also notice that the Submit button, previously located at the top of the form, has disappeared.
- Important: the next step is to add yourself to the application as a team member. This must be done before you close the application. Failing to do so will result in you losing access to the application.


Save
Close
Print
Export to Word
Export to PDF
?
* Project Info
Project Team Info
* HEALTH SCIENCES RESEARCH ETHICS BOARD APPLICATION FORM for ETHICS CLEARANCE
Attachments
Approvals
Logs
Errors
Principal Investigator
Instructions : Do not hand type data for this section. The Principal Investigator (PI) section default populates with the researcher profile data for the project team member who creates the file. If you are not the PI, click the Change PI button to search for and select an alternate researcher profile. If you load an alternate researcher profile to the PI section, be sure to reload your researcher profile to the Other Project Team Info section below.
Change PI
Refresh
Prefix:
Dr.
Last Name*:
Investigator
First Name*:
Principal
Affiliation*:
Faculty of Health Sciences\Biomedical and Molecular Sciences

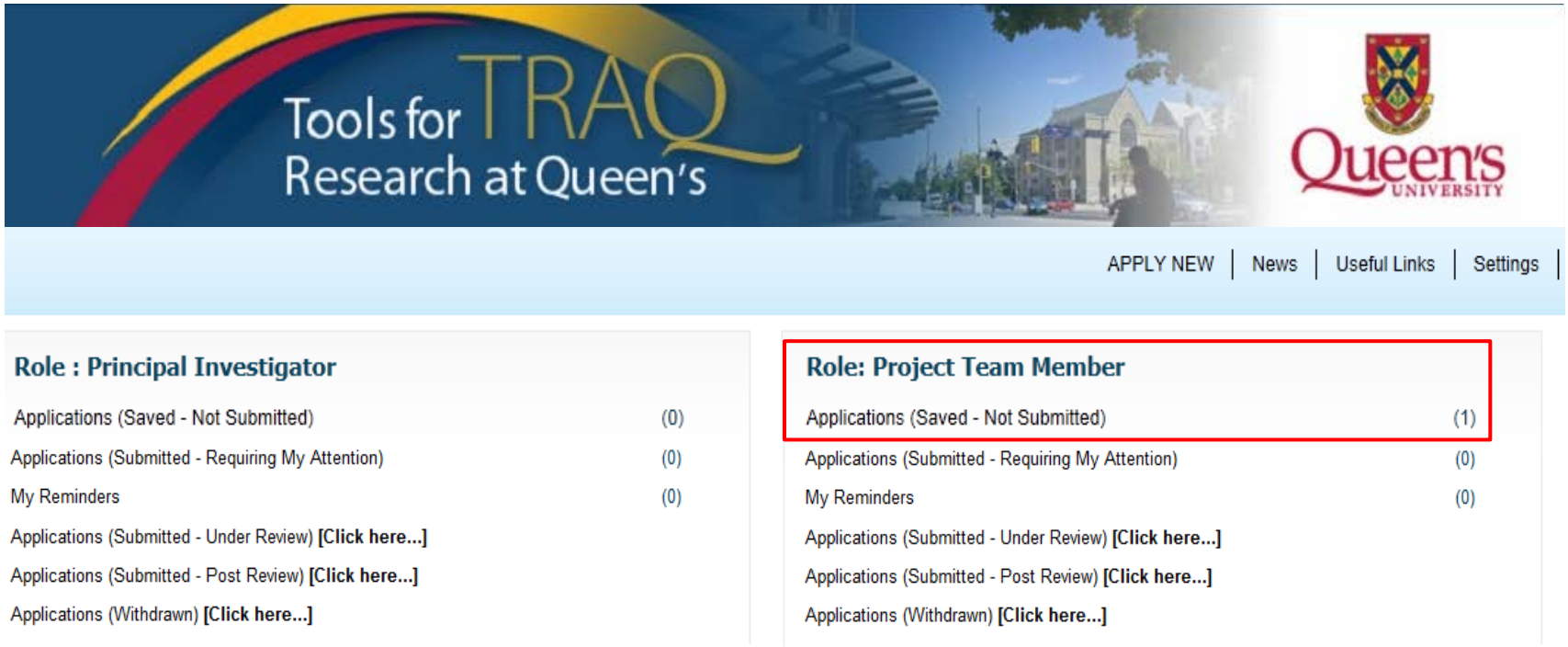
Project Info tab - Adding Project Team Members

- Scroll down to Other Project Member Info on the Project Team Info tab and click Add New. Click on Search Profiles and repeat the search process, this time assigning yourself to the team and selecting your role in the study from the Role in Project drop down menu.

- Applicants may add as many team members as required by clicking Add New, team member information can be edited or deleted as required. Again, please contact the TRAQ Helpdesk by email if you are unable to locate the team member in the Investigators List.

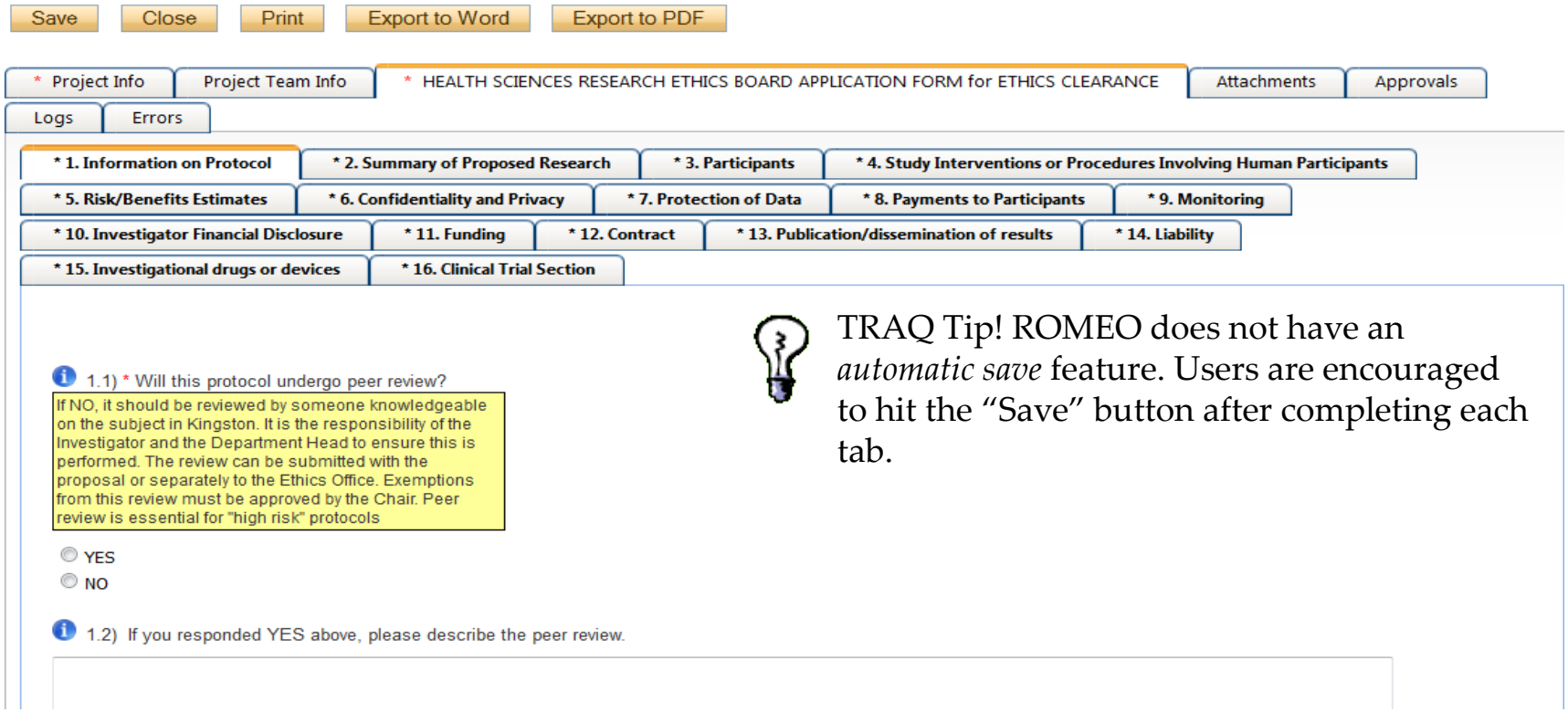
P.I. Role versus Project Team Member Role

- Once the change has been made on the Project Team Info tab, the application will be accessible to the Research Coordinator and to the other team members from the TRAQ Researcher Portal under **Role: Project Team Member**.
- The PI is the only person who can submit the application once it has been completed by the Research Coordinator.


Tools for TRAQ
Research at Queen's
Queen's UNIVERSITY
APPLY NEW | News | Useful Links | Settings
Role : Principal Investigator
Applications (Saved - Not Submitted) (0)
Applications (Submitted - Requiring My Attention) (0)
My Reminders (0)
Applications (Submitted - Under Review) [Click here...]
Applications (Submitted - Post Review) [Click here...]
Applications (Withdrawn) [Click here...]
Role: Project Team Member
Applications (Saved - Not Submitted) (1)
Applications (Submitted - Requiring My Attention) (0)
My Reminders (0)
Applications (Submitted - Under Review) [Click here...]
Applications (Submitted - Post Review) [Click here...]
Applications (Withdrawn) [Click here...]

Health Sciences Research Ethics Board Application Form tab

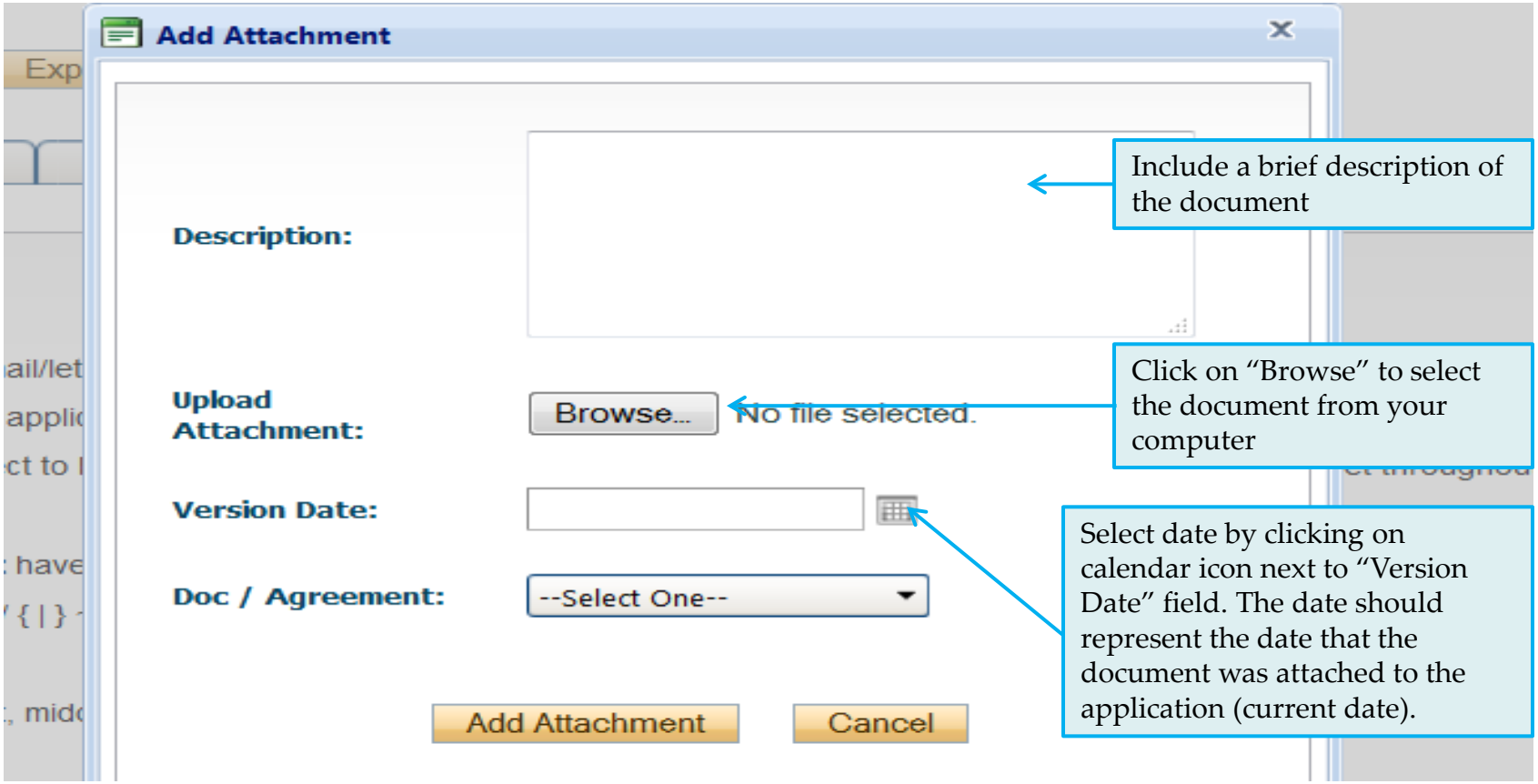
- This tab has several sub-tabs all of which contain required questions. If you are unsure how to answer a question, try clicking on the info tab ( ) additional information may be available as seen in the screenshot below!


Save
Close
Print
Export to Word
Export to PDF
* Project Info
Project Team Info
* HEALTH SCIENCES RESEARCH ETHICS BOARD APPLICATION FORM for ETHICS CLEARANCE
Attachments
Approvals
Logs
Errors
* 1. Information on Protocol
* 2. Summary of Proposed Research
* 3. Participants
* 4. Study Interventions or Procedures Involving Human Participants
* 5. Risk/Benefits Estimates
* 6. Confidentiality and Privacy
* 7. Protection of Data
* 8. Payments to Participants
* 9. Monitoring
* 10. Investigator Financial Disclosure
* 11. Funding
* 12. Contract
* 13. Publication/dissemination of results
* 14. Liability
* 15. Investigational drugs or devices
* 16. Clinical Trial Section
1.1) * Will this protocol undergo peer review?
If NO, it should be reviewed by someone knowledgeable on the subject in Kingston. It is the responsibility of the Investigator and the Department Head to ensure this is performed. The review can be submitted with the proposal or separately to the Ethics Office. Exemptions from this review must be approved by the Chair. Peer review is essential for "high risk" protocols
YES
NO
1.2) If you responded YES above, please describe the peer review.

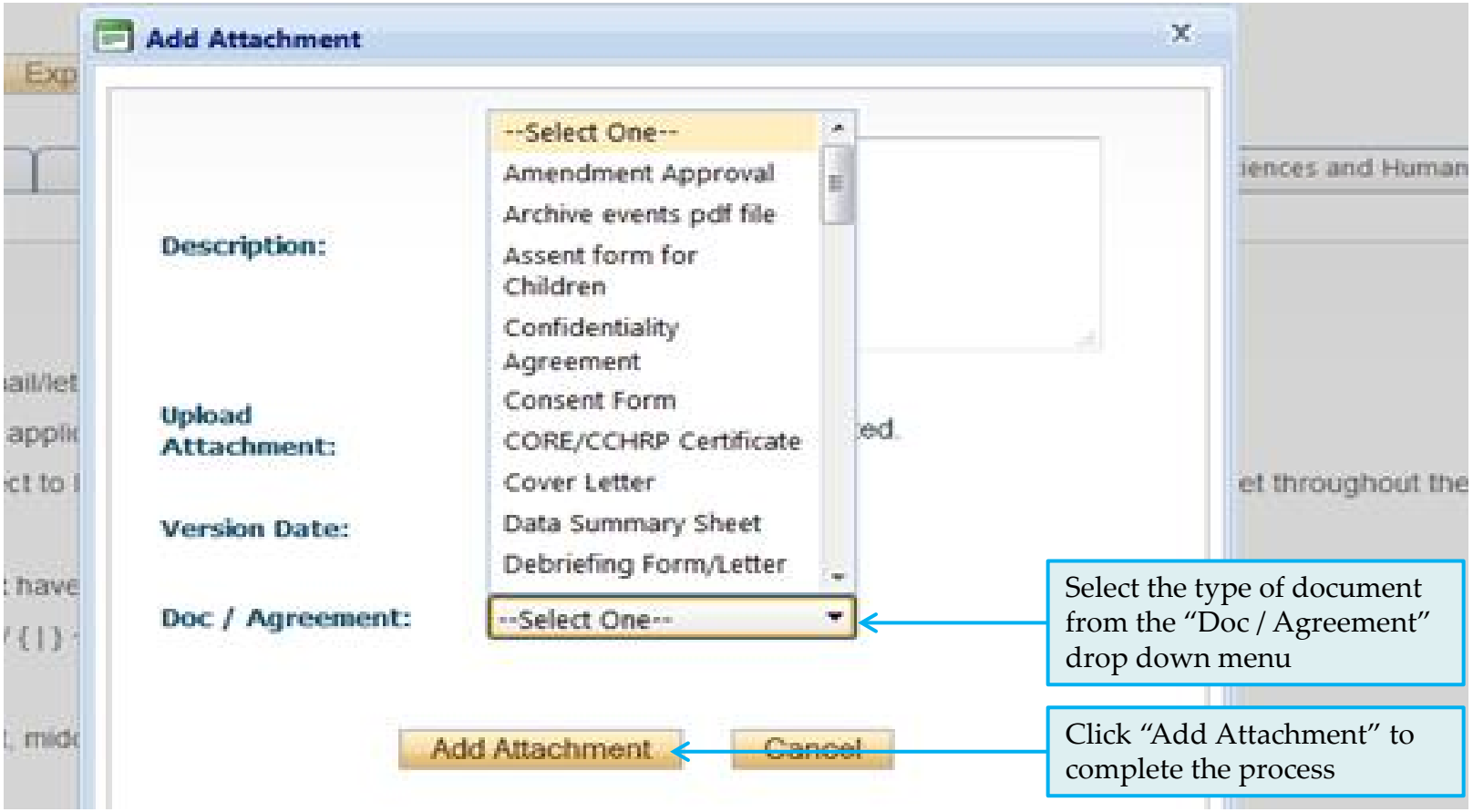
TRAQ Tip! ROMEO does not have an *automatic save* feature. Users are encouraged to hit the "Save" button after completing each tab.

Attachments tab

- Applicant should attach any document(s) identified on the Checklist sub-tab of the Ethics Form. Users may upload multiple attachments, provided that each is no larger than 5MB. Attachments may be word files, spreadsheets, jpeg files, pdfs, etc.

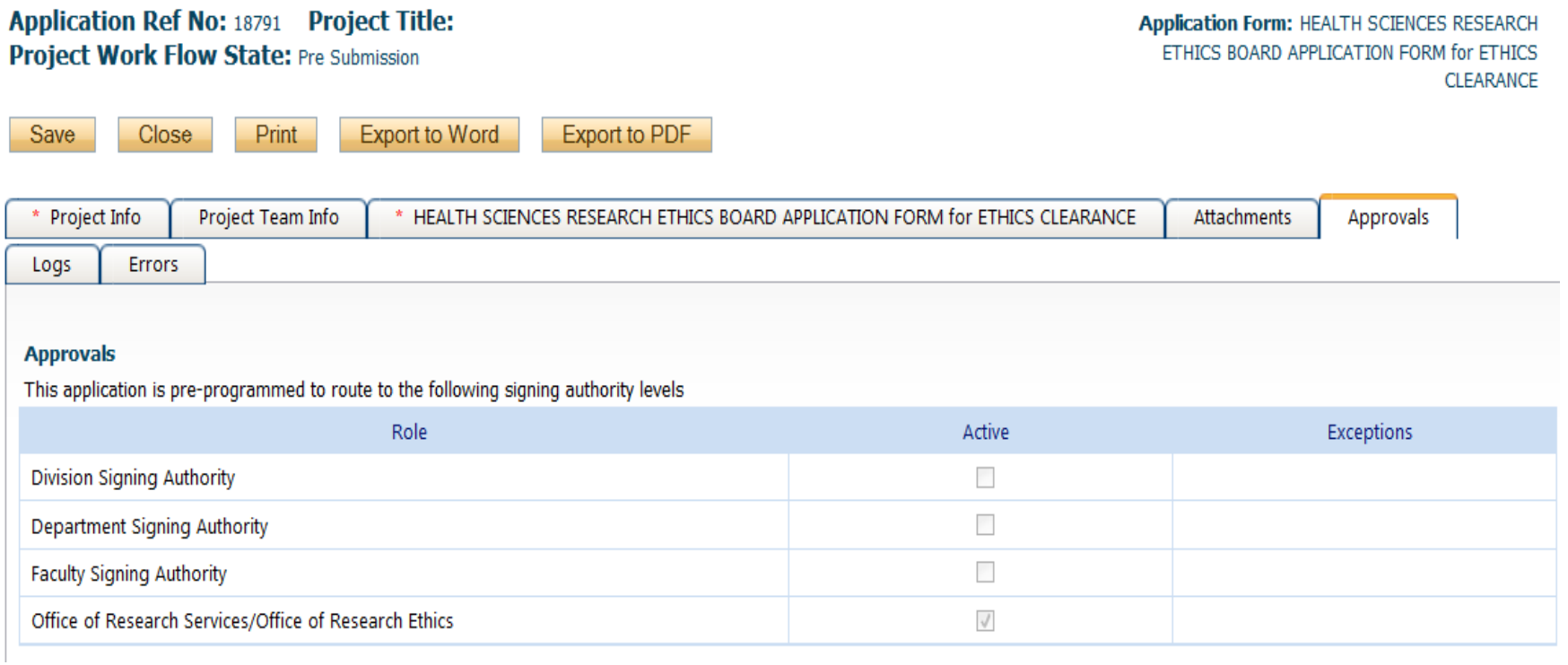

Add Attachment
Description:
Upload Attachment:
Browse...
No file selected.
Version Date:
Doc / Agreement:
--Select One--
Add Attachment
Cancel
Include a brief description of the document
Click on "Browse" to select the document from your computer
Select date by clicking on calendar icon next to "Version Date" field. The date should represent the date that the document was attached to the application (current date).

Attachments tab (Cont.)



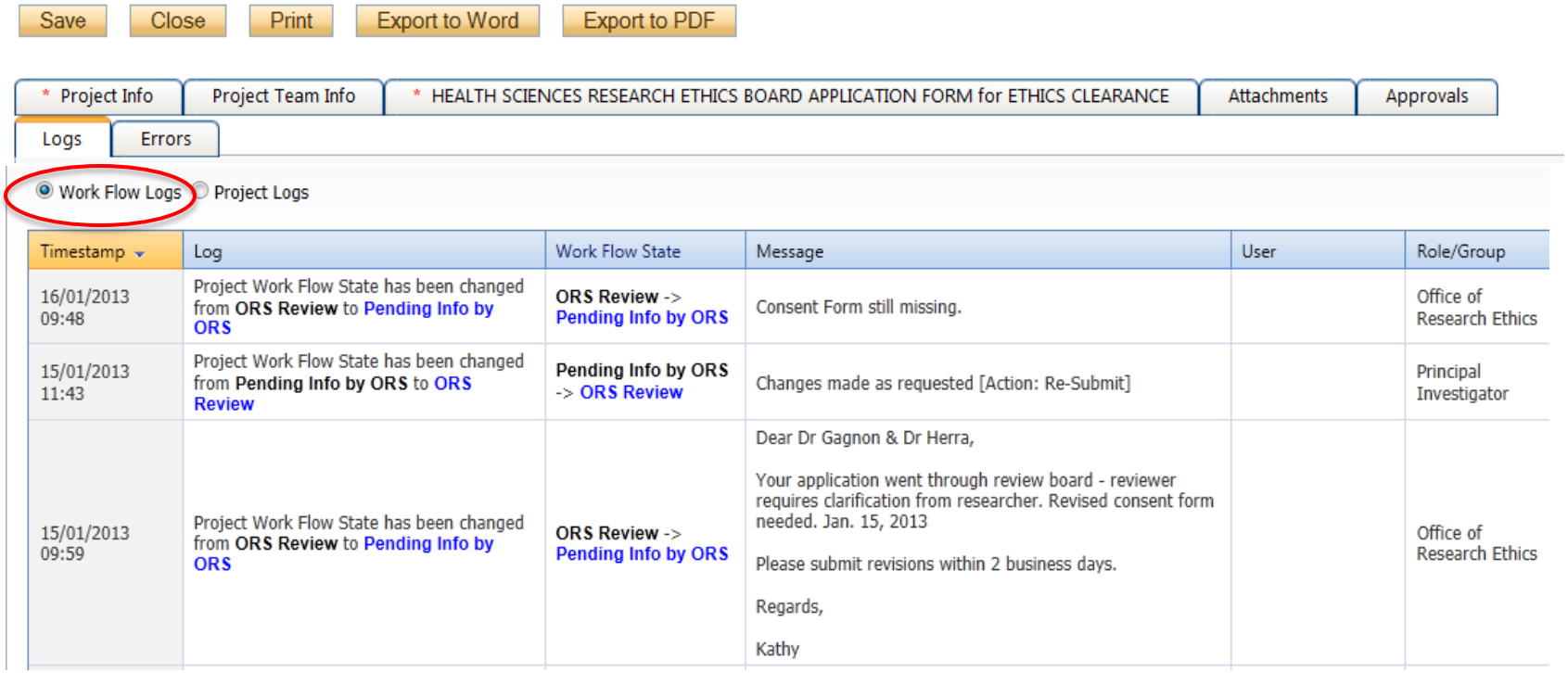
Approvals tab

- The Approvals tab simply describes the workflow of an application in TRAQ. For example, this HSREB application will be submitted straight to the HSREB (Office of Research Services/Office of Research Ethics). This workflow is pre-determined. You may skip this tab.



Logs tab – Workflow Logs

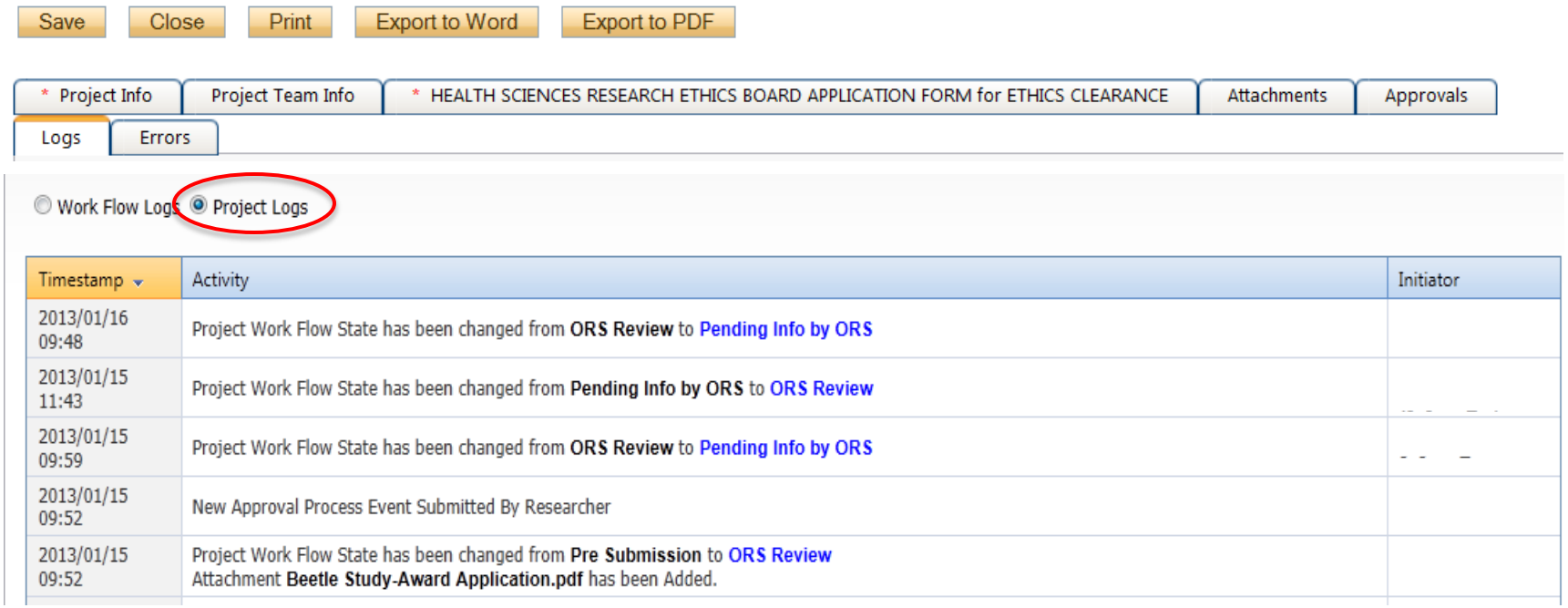
- The Logs tab is a useful tool that allows the applicant(s), reviewer(s) and the Ethics Office to track the history of the application and communicate with one another. Text in blue font represents most recent updates
- The Workflow Logs tracks and time stamps approvals and messages



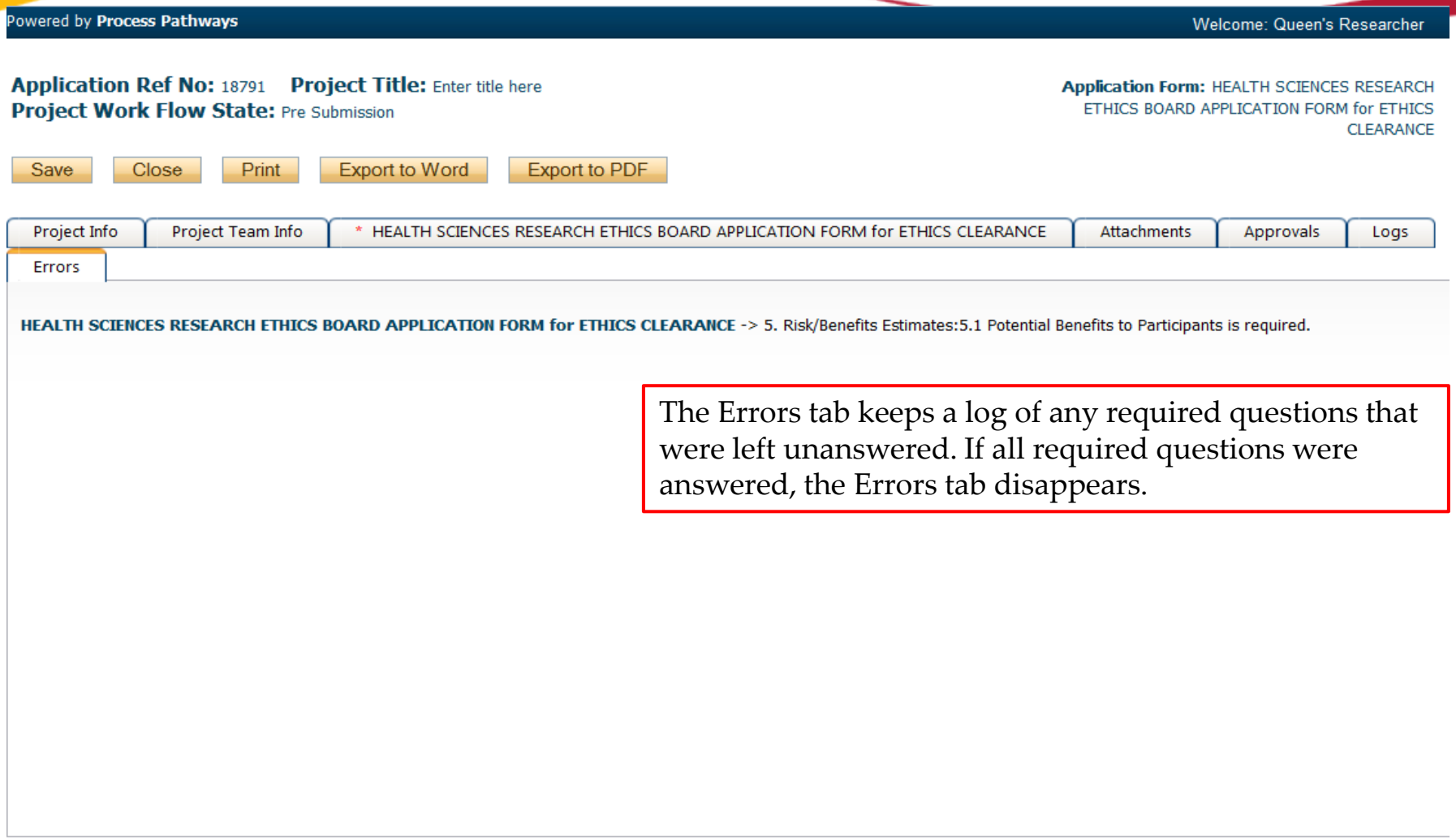
Timestamp	Log	Work Flow State	Message	User	Role/Group
16/01/2013 09:48	Project Work Flow State has been changed from **ORS Review** to **Pending Info by ORS**	**ORS Review** -> **Pending Info by ORS**	Consent Form still missing.		Office of Research Ethics
15/01/2013 11:43	Project Work Flow State has been changed from **Pending Info by ORS** to **ORS Review**	**Pending Info by ORS** -> **ORS Review**	Changes made as requested [Action: Re-Submit]		Principal Investigator
15/01/2013 09:59	Project Work Flow State has been changed from **ORS Review** to **Pending Info by ORS**	**ORS Review** -> **Pending Info by ORS**	Dear Dr Gagnon & Dr Herra, Your application went through review board - reviewer requires clarification from researcher. Revised consent form needed. Jan. 15, 2013 Please submit revisions within 2 business days. Regards, Kathy		Office of Research Ethics

Logs tab – Project Logs

- The Project Logs tracks and time stamps every action taken on the application.


Save
Close
Print
Export to Word
Export to PDF
* Project Info
Project Team Info
* HEALTH SCIENCES RESEARCH ETHICS BOARD APPLICATION FORM for ETHICS CLEARANCE
Attachments
Approvals
Logs
Errors
Work Flow Logs
Project Logs
Timestamp
Activity
Initiator
2013/01/16 09:48
Project Work Flow State has been changed from ORS Review to Pending Info by ORS
2013/01/15 11:43
Project Work Flow State has been changed from Pending Info by ORS to ORS Review
2013/01/15 09:59
Project Work Flow State has been changed from ORS Review to Pending Info by ORS
2013/01/15 09:52
New Approval Process Event Submitted By Researcher
2013/01/15 09:52
Project Work Flow State has been changed from Pre Submission to ORS Review
Attachment Beetle Study-Award Application.pdf has been Added.

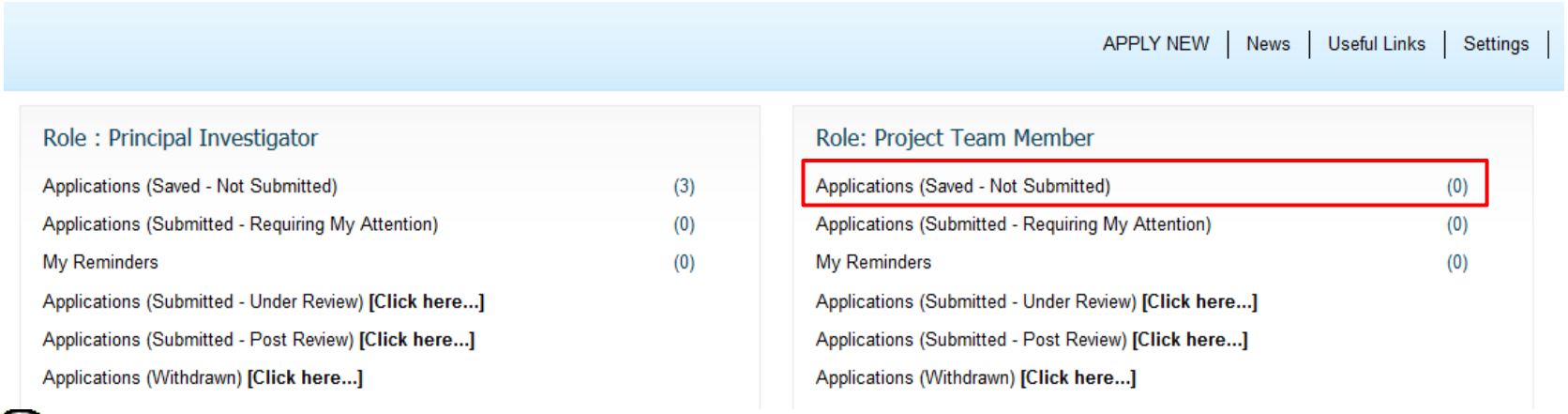
Errors tab


Powered by Process Pathways
Welcome: Queen's Researcher
Application Ref No: 18791 Project Title: Enter title here
Project Work Flow State: Pre Submission
Application Form: HEALTH SCIENCES RESEARCH ETHICS BOARD APPLICATION FORM for ETHICS CLEARANCE
Save
Close
Print
Export to Word
Export to PDF
Project Info
Project Team Info
* HEALTH SCIENCES RESEARCH ETHICS BOARD APPLICATION FORM for ETHICS CLEARANCE
Attachments
Approvals
Logs
Errors
HEALTH SCIENCES RESEARCH ETHICS BOARD APPLICATION FORM for ETHICS CLEARANCE -> 5. Risk/Benefits Estimates:5.1 Potential Benefits to Participants is required.

The Errors tab keeps a log of any required questions that were left unanswered. If all required questions were answered, the Errors tab disappears.

Save and Continue…

- At any point in the process, the applicant may Save and Close the application and complete it at a later date. The information entered will be saved and the user can access it again through the TRAQ Researcher Portal under **Applications (Saved – Not Submitted)**. Important: Do not close that application by clicking the X at the top of your browser, doing so will result in the application being locked preventing other team members from accessing it


APPLY NEW | News | Useful Links | Settings
Role : Principal Investigator
Applications (Saved - Not Submitted) (3)
Applications (Submitted - Requiring My Attention) (0)
My Reminders (0)
Applications (Submitted - Under Review) [Click here...]
Applications (Submitted - Post Review) [Click here...]
Applications (Withdrawn) [Click here...]
Role: Project Team Member
Applications (Saved - Not Submitted) (0)
Applications (Submitted - Requiring My Attention) (0)
My Reminders (0)
Applications (Submitted - Under Review) [Click here...]
Applications (Submitted - Post Review) [Click here...]
Applications (Withdrawn) [Click here...]

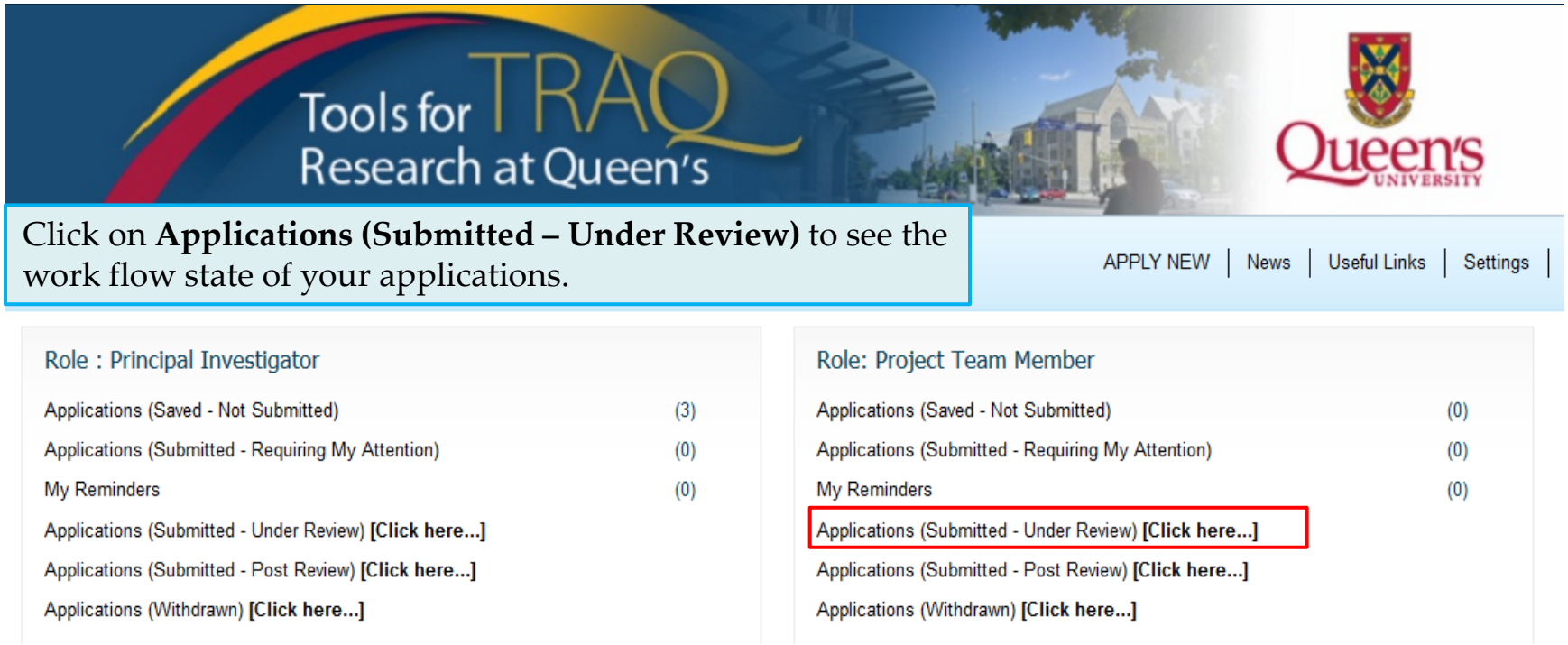
TRAQ Tip! Though ROMEO has no *automatic save* feature, it does have a *time out* feature! If you need to step away from your computer, you should always hit the Save and Close buttons as a precautionary measure. Failing to do so could result in information being lost and the application being locked. The user responsible for locking the application is able to unlock it by accessing it again and exiting properly. All other team members, who find themselves locked out of the application, can either contact the user who locked it or the TRAQ team for support (ext. 78426; email: traq@queensu.ca)

Submitting the Application

- From the moment you assign another PI and team members to the project, they will be able to view and edit the application.
- The PI is the only person who can submit the application, this cannot be done on their behalf.
- The team member responsible for completing the application should notify the PI when the application is ready to be reviewed and submitted.
- Once the application has been submitted, the PI will receive an email confirming the reception of the application – any team member associated with the application will be copied on the correspondence.

Applications Under Review

- Once the PI has submitted the application for review, it is still available for viewing under **Role: Project Team Member Applications (Submitted – Under Review)**


Tools for TRAQ
Research at Queen's
Queen's UNIVERSITY
Click on **Applications (Submitted – Under Review)** to see the work flow state of your applications.
APPLY NEW | News | Useful Links | Settings
Role : Principal Investigator
Applications (Saved - Not Submitted) (3)
Applications (Submitted - Requiring My Attention) (0)
My Reminders (0)
Applications (Submitted - Under Review) [Click here...]
Applications (Submitted - Post Review) [Click here...]
Applications (Withdrawn) [Click here...]
Role: Project Team Member
Applications (Saved - Not Submitted) (0)
Applications (Submitted - Requiring My Attention) (0)
My Reminders (0)
Applications (Submitted - Under Review) [Click here...]
Applications (Submitted - Post Review) [Click here...]
Applications (Withdrawn) [Click here...]

Work Flow State of Applications Under Review

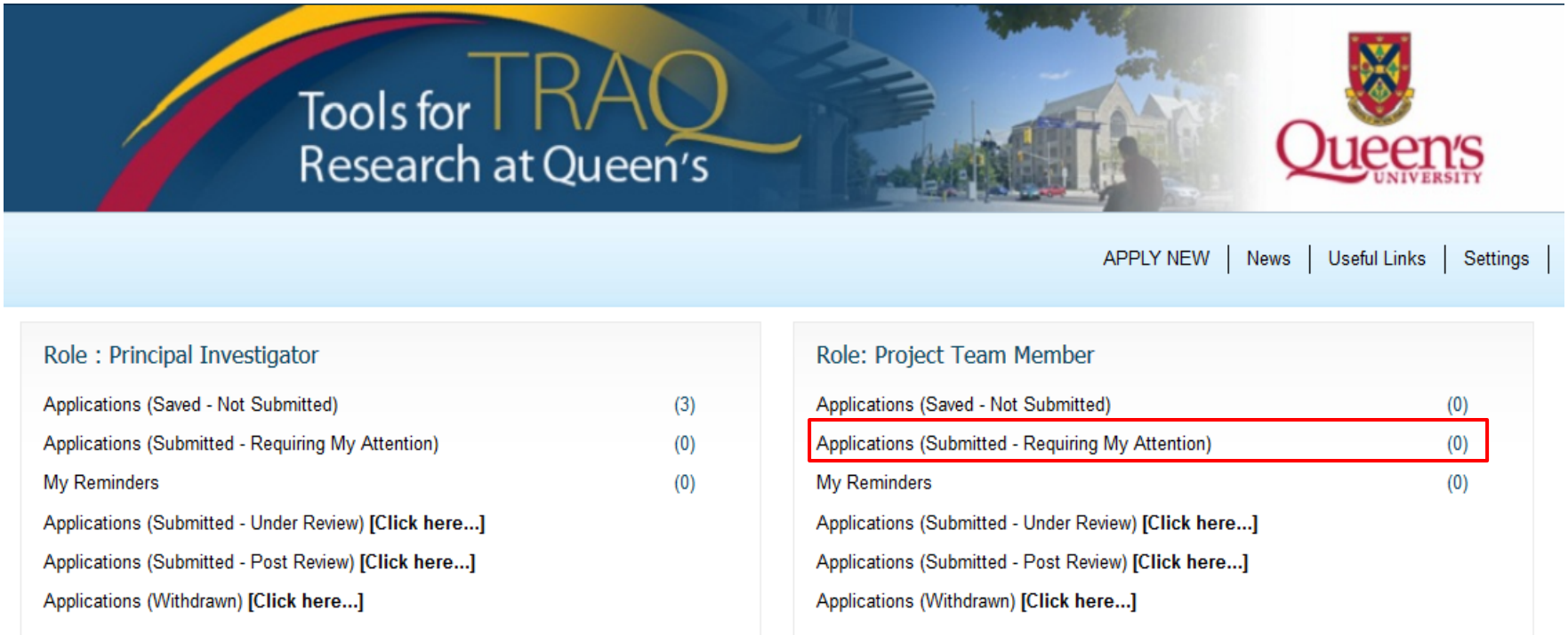
- Check the status of your application(s) under review under the Status Snapshot column.
- In the example below, the HSREB application is pending approval from HSREB (Workflow Status: ORS Review).

Reset Filters Export To Excel

	File No	Project Title	Principal Investigator	Application Type	Status Snapshot	Workflow Message
				All		
View Clone	**Ref No : 18790**	Enter title	Dr. Principal Investigator (Faculty of Health Sciences\Biomedical and Molecular Sciences)	HEALTH SCIENCES RESEARCH ETHICS BOARD APPLICATION FORM for ETHICS CLEARANCE (Certification\Human Ethics)	**Project Status**: Pending **Workflow Status**: ORS Review	Please review [Action: Submit]

Applications Requiring Revisions

- If the reviewer(s) require any revisions, the application will be pushed back to the applicant(s). At this stage, you will be able to edit the application by clicking on **Applications (Submitted – Requiring my Attention)**. The PI, Research Coordinator and Supervisor will receive an automatic email notifying them that they have an application which requires their attention. Any member of the team will be able to edit the application, but the PI is the only person who has the ability to re-submit the application.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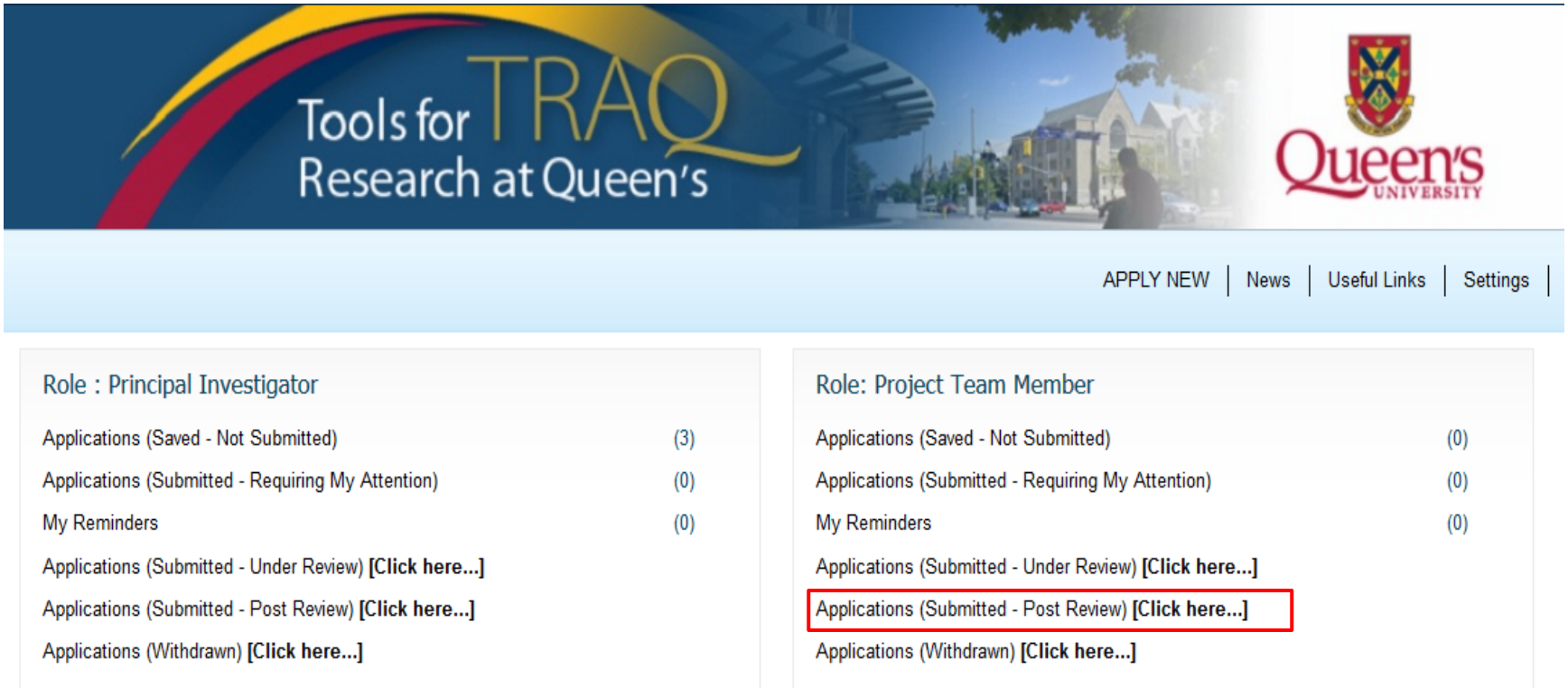
Applications (Submitted - Post Review) [Click here...]
Applications (Withdrawn) [Click here...]
Role: Project Team Member
Applications (Saved - Not Submitted) (0)
Applications (Submitted - Requiring My Attention) (0)
My Reminders (0)
Applications (Submitted - Under Review) [Click here...]
Applications (Submitted - Post Review) [Click here...]
Applications (Withdrawn) [Click here...]

Approved Applications

- Once the application has been approved, the PI, Research Coordinator and Supervisor will receive a formal approval letter and email. The application can no longer be modified but is available for viewing under **Applications (Submitted – Post Review)**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Applications (Withdrawn) [Click here...]
Role: Project Team Member
Applications (Saved - Not Submitted) (0)
Applications (Submitted - Requiring My Attention) (0)
My Reminders (0)
Applications (Submitted - Under Review) [Click here...]
Applications (Submitted - Post Review) [Click here...]
Applications (Withdrawn) [Click here...]

Need assistance/have a question?

Contact the TRAQ Helpdesk

(613) 533-6000, ext. 78426

Email: traq@queensu.ca